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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/156,804      09/17/98      KALTENBACH

F      10980096-1

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AGILENT TECHNOLOGIES  
LEGAL DEPARTMENT, 51UPD  
INTELLECTUAL PROPERTY ADMINISTRATION  
P.O. BOX 58043  
SANTA CLARA CA 95052-8043

EXAMINER

BEX, P

ART UNIT

PAPER NUMBER

10

1743

DATE MAILED:

10/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/156,804

Applicant(s)

Kaltenbach et al.

Examiner  
Patricia Kathryn Bex

Group Art Unit  
1743



☒ Responsive to communication(s) filed on Aug 4, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) 13-24 and 27 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-12, 25, and 26 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restriction***

1. This application contains claims 13-24 and 27 which are drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 U.S.C. § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-12 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The addition of the new limitation "upon application of a driving force resulting from simultaneous operative and modular coupling" introduces new matter. Applicant cites page 10, line 14 to page 11, line 17 as support for this new limitation. However, these pages simply describe a membrane coving the reservoirs which can be punctured by a protrusion arm on the separation unit which allows fluid "to flow" from the reservoir into the separation unit. There is no mention of a "driving force" which results from the "simultaneous" operative and modular

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coupling. The only "driving force" described in the specification results from the power unit 110 and probes 112b for applying the driving force to drive movement of chemicals from the reservoir through the microchannel.

***Claim Rejections - 35 U.S.C. § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1- 4, 6-7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) in view of Baker et al. (USP 4,654,127).

Swedberg teaches a separation unit 2 having a microchannel, in which the analyte can be driven to pass through the microchannel 10 due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel being indicative of the molecular characteristics of the analyte and a reservoir unit having one or more reservoirs with

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dimensions compatible with the separation unit operatively and modularly coupled to the separation unit to supply liquid reagents thereto (column 29, lines 47-56). Swedberg does not teach that the reservoirs are prepackaged liquid reagents and analyte therein before the reservoir unit is coupled with the separation unit and upon application of a driving force from simultaneous operative and modular coupling. Baker does teach a unit 12 having a microchannel 20, in which the analyte can be driven to pass through the microchannel and a reservoir unit 36 having one or more reservoirs 40, 42 having dimensions compatible with the unit operatively and modularly coupled to the unit to supply liquid reagents and analytes thereto upon application of a driving force, resulting from simultaneous operative and modular coupling (Figs. 5A-5B), the reservoirs having prepackaged liquid reagents therein before the reservoir unit is coupled to the unit. Further, the reservoir unit includes 126, 128 membranes covering the reservoirs confining the prepackaged liquid reagent therein (col. 4, lines 4-48, Figs. 2-8).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg prepackaged liquid reagents and analytes, as taught by Baker, in order to ensure that the reagents avoid contamination before introduction in the microchannel and eliminates the need for handling of calibrated reagents (col. 2, lines 50-51).

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7. Claims 5, 8-9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) in view of Baker et al. (USP 4,654,127), as applied to claim 2 above, and in further view of Kambara et al. (USP 5,968,331).

8. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) and Baker et al. (USP 4,654,127) and Kambara et al. (USP 5,968,331), as applied to claim 26, and further in view of Kaltenbach et al. (USP 5,641,400).

See previous Office Action.

#### ***Response to Arguments***

9. Applicant's arguments filed August 9, 2000 have been fully considered but they are not persuasive.

In response to the rejection of claims 1- 4, 6-7 and 25 under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) in view of Baker et al. (USP 4,654,127) Applicant argues that Baker et al. do not teach a separation unit but rather a device for clinical chemistry. Examiner points out that Swedberg et al. is relied upon for the teaching of a separation unit (see abstract). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a

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prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Applicant argues that neither Baker et al. or Swedberg et al. disclose the limitation “simultaneous operative and modular coupling that results in a driving force”. The Baker et al. device employs an action distinct from a driving force resulting from simultaneous operative and modular coupling, e.g., turning to a “start position”. Examiner reminds Applicant that the phrase “modularly coupling” is defined in the specification as an apparatus containing various parts or components which can be assembled for use at the point of use without extensive calibration or testing, see page 6, lines 2-4. Therefore, the turning of the reservoir unit 36 which is placed into the start position does read on the limitation “simultaneous operative and modular coupling” since these components 36, 76 and 22 are simultaneously assembled without extensive calibration or testing when placed into the start position. The driving forces involved in Baker et al. are capillary and hydraulic head (column 9, lines 53-58).

### ***Conclusion***

10. No claims allowed.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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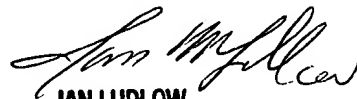
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



P. Kathryn Bex  
Patent Examiner  
Art Unit 1743  
October 10, 2000



JAN LUDLOW  
PRIMARY EXAMINER